

REMARKS

Claims

Claims 1, 19 and 28 have been amended. The amended claims more clearly define the invention for which protection is sought.

Claim Rejections – 35 U.S.C. 103

Byram and Nelson

The Examiner has rejected claims 1-6, 10-15, 19-24 and 28 under 35 U.S.C. 103 as being obvious when Byram (U.S. patent no. 6,591,837) is considered in view of Nelson (US 4,960,121). The Examiner reaches this conclusion by stating that Byram discloses the Applicant's invention as claimed with the exception of disclosing an adaptor for receiving oxygen tubing and that Nelson discloses such an adaptor. The Examiner states that it would have been obvious to modify Byram's invention to receive oxygen tubing as taught by Nelson.

The Applicant respectfully disagrees. The Applicant argued, in its first office action response, that Byram can be distinguished from the present invention because Byram does not teach the use of an oxygen mask. The Examiner has, it appears, repeated the argument that a respirator is an oxygen mask, as was done in the first office action, and has not taken note of, or responded to, the substance of the Applicants arguments, as required by §707.07 of the MPEP. Therefore the Applicant reiterates these arguments. As stated in our office action response filed November 17, 2004:

The Examiner has equated the respirator of Byram with the oxygen mask that is now a positive limitation of the method claimed. The Applicant submits that the respirator of Byram cannot properly be equated with the oxygen mask claimed in the present invention. A respirator and an oxygen mask have a different function, and although a respirator may be adapted to accommodate an oxygen source, it is still a respirator, and not an oxygen mask. The Applicant submits that Byram does not disclose oxygen masks.

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Byram does not mention oxygen masks, but rather is directed exclusively towards respirators. A "respirator" is an apparatus worn over the face to prevent the breathing in of dust, smoke, or other harmful substances, or an apparatus used to provide artificial respiration. Byram states that there are two important reasons for wearing a respirator: to protect the respiratory tract from contaminants in the environment, or to protect others from contaminants exhaled by the wearer of the respirator. Had Byram intended to include oxygen masks within the scope of his invention, he could have done so, as oxygen masks were well known at that time that the application was filed. The meaning of this reference to someone of ordinary skill in the art is clear and unambiguous- it relates to respirators.

An oxygen mask is designed to deliver oxygen to the wearer of the mask, and includes an adaptor for the attachment of tubing that is connected to a supply of oxygen. Such a mask is shown in the Figures of the present application. Byram makes no mention of the delivery of oxygen to the wearer of the respirator.

Byram is directed towards providing a new respirator and strap combination that can be used to conveniently dispose the respirator beneath a wearer's chin, when it is not in use. The problem being addressed by Byram relates to the fact that people who wear respirators repeatedly remove and replace the respirator over their mouth and nose. Byram provides a means of retaining a respirator in a convenient location, when removed from a wearer's face, so that it can be quickly and easily retrieved and returned to its position over the wearer's mouth and nose.

Byram is not concerned with and does not mention the problem of ear abrasion, which results from the chronic, long-term and continuous wearing of an oxygen mask, as occurs in persons who wear oxygen masks for extended periods of time, often in a hospital setting.

The Applicant submits that the added limitations to claims 1 and 10 render these claims novel over Byram. As claims 2, 3, 5, 11, 12 and 14 depend either directly or indirectly from claims 1 and 10, the Applicant submits that these claims are

likewise novel over Byram. Favorable consideration and withdrawal of the rejections to these claims under 35 U.S.C. 102 is respectfully requested.
[emphasis added]

Therefore, the Applicant submits that the Examiner's contention that a Byram discloses the invention, as claimed, except for an adaptor, is incorrect, because Byram does not disclose the use of an oxygen mask. Therefore, adding the adapter of Nelson to the respirator of Byram will not lead to the invention, as claimed, as the claimed invention is directed towards an oxygen mask and a methods of avoiding ear abrasion resulting from the long-term wearing thereof.

The nature of the problem to be solved is different in Byram as compared to the problem that the claimed invention solves. Byram relates to the fact that people who wear respirators repeatedly remove and replace the respirator over their mouth and nose. The reference provides a strap that makes this removal and replacement more convenient. The present invention relates to the problem of ear abrasion that results from persons wearing medical oxygen masks over an extended period of time, as in discussed in the background section and as is claimed. Therefore, a person seeking to avoid ear abrasions resulting from long term chronic wearing of a medical oxygen mask, would not be motivated to combine Byram with Nelson, as neither of these references is concerned with oxygen delivery, or with the side effects from the long term wearing of medical oxygen masks. The prior art and the claimed invention do not share the same utility, and where the prior art does not teach the utility asserted in the claimed invention, there can be no motivation to combine references for that utility- see *In re. Lalu* (1984).

The test for obviousness is what the combined teachings of the references would have suggested to those of skill in the art- see *In re Keller* (1981). The combination of Byram and Nelson in no way suggests that the strap disclosed in either of these two documents could be used on a medical oxygen mask to avoid ear abrasion. These two documents are concerned with providing an easy way to remove and put on a respirator.

The Applicant notes once again that Norfleet (US 6,418,929), which is the most analogous art cited, teaches away from the claimed invention. Norfleet suggests that, in the case where a medical oxygen mask with oxygen supply tubing is being secured, a single connection point may result in flipping of the mask when the person wearing the mask moves around. In essence, Norfleet explains why these inventors did **not** use a strap that has only one connection point to the medical oxygen mask on either side, but rather chose to use two connection points. The reason is that they believed that the mask would flip over. Surely this evidences the non-obviousness of the claimed invention and is directly contradictory to the Examiner's contention that it would have simply been obvious to combine Byram and Nelson to arrive at the invention claimed.

For the above reasons, the Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness. The prior art references cannot be properly combined or modified to arrive at the invention claimed because there is no suggestion or motivation to combine the references and there is no reasonable expectation of success. Further, even if combined, all the claim limitations are not satisfied.

Further, the attached Declaration provides objective evidence of nonobviousness.

The attached Declaration evidences the long-felt need to solve this problem. This document shows that the problem of ear abrasion from wearing medical oxygen masks is real in the health care industry, that it is a long-standing problem, and that no one has devised a way to avoid this problem. If it were an obvious solution to use the strap of Byram on a medical oxygen mask, or to combine Byram and Nelson references to arrive at the claimed invention, as the Examiner has suggested, then surely this would have been done.

The prior art must provide a reasonable expectation that the proposed modification will succeed- see *In re Dow Chem. Co.*. The Declaration by the inventor which is provided herewith, evidences that a Clinical Trial of the strap claimed was performed to demonstrate that it actually works in a clinical setting. There was concern that it may not hold the mask in the right position to deliver oxygen, and this was shown not to be the case with the Clinical Trial. Expressions of disbelief by experts, such as the

evidence that a Clinical Trial was performed, and such as the comments by Norfleet noted above, constitute strong evidence of nonobviousness – see *Environmental Designs v. Union Oil* (1983).

The Declaration by the inventor also provides evidence that the product will be commercially successful.

In summary, it is submitted that:

- the use of a medical oxygen mask cannot be extrapolated from Byram or Nelson alone or in combination;
- the fact that the strap disclosed in the present application could be used in combination with a medical oxygen mask was demonstrated by a clinical trial, which evidences initial disbelief that the invention claimed would work;
- there is a long-felt need for a solution to the problem of ear abrasion resulting from wearing medical oxygen masks;
- the prior art (Norfleet) teaches away from the invention claimed;
- the claimed invention is effective where alternative measures, all of which treat rather than avoid the problem, are not;
- the claimed invention will fill the long-felt need, leading to commercial success.

Therefore, the Applicant submits in view of the above arguments and evidence, that claims 1-6, 10-15, 19-24 and 28 are not obvious in view of Byram and Nelson. Favorable consideration and withdrawal of the rejections to these claims under 35 U.S.C. 103 is respectfully requested.

Byram and Darrow

The Examiner has rejected claims 7, 16, 25 and 29 under 35 U.S.C. 103 as being obvious when Byram is considered in view of Darrow (US 1,323,217). The Examiner reaches this conclusion by stating that Byram discloses the Applicant's invention as

claimed in these claims, with the exception of disclosing a transverse element, and that Darrow discloses such a transverse element.

Clearly, the Examiner's rejection is incorrect. Claims 7, 16, 25 and 29 depend, directly or indirectly from independent claims 1, 10, 19 and 28. The Examiner was of the opinion, earlier in the office action that Byram did not teach all elements of these claims as Byram did not teach an adaptor for receiving oxygen supply tubing, which was taught by Nelson. The Examiner is now contending that Byram teaches the adaptor.

The undersigned called the Examiner on February 9, 2006 seeking clarification, but has not received any response clarifying this rejection. Therefore, the Applicant presumes that the rejection of claims 7, 16, 25 and 29 is properly based on a combination of Byram and Nelson and Darrow, as that is the only rejection that would make sense.

The Applicant submits that in view of the above arguments for claims 1-6, 10-15, 19-24 and 28, the rejection is not relevant. Favorable consideration and withdrawal of the rejections to these claims under 35 U.S.C. 103 is respectfully requested.

Byram and Norfleet

The Examiner has rejected claim 30 under 35 U.S.C. 103 as being obvious when Byram is considered in view of Norfleet (US 6,418,929). The Examiner reaches this conclusion by stating that Byram discloses the Applicant's invention as claimed in this claim, with the exception of disclosing upper and lower crown straps that comprise elastic material, and that Norfleet discloses such upper and lower crown straps.

Again, the Examiner's rejection is clearly incorrect. Claim 30 depends from claim 29 which depends from claim 28. The Examiner was of the opinion, earlier in the office action, that Byram did not teach all elements of claim 28, as Byram did not teach an adaptor for receiving oxygen supply tubing, which was taught by Nelson. Further, the Examiner was of the view that Byram did not teach all elements of claim 29, as Byram did not teach a transverse element which was taught by Darrow. The Examiner is now contending that Byram teaches both the adaptor and the transverse element.

The undersigned called the Examiner on February 9, 2006 seeking clarification, but has not received any response clarifying this rejection. Therefore, the Applicant presumes that the rejection of claim 30 is properly based on a combination of Byram and Nelson and Darrow and Norfleet, as that is the only rejection that would make sense.

The Applicant submits that in view of the above arguments for claims 1-6, 10-15, 19-24 and 28, the rejection is not relevant. Favorable consideration and withdrawal of the rejections to these claims under 35 U.S.C. 103 is respectfully requested.

Byram, Darrow and Cruickshank

The Examiner has rejected claims 8, 9, 17, 18, 26, 27 and 31 as being unpatentable over Byram in view of Darrow and Cruickshank (U.K. application no. 2,212,725). The Examiner reaches this conclusion by stating that Byram and Darrow disclose the Applicant's invention as claimed in claims 7, 16, 25 and 29 with the exception of disclosing a transverse crown strap that comprises resilient (elastic) material, and Cruickshank discloses a transverse crown strap that comprises a resilient (elastic) material.

Again, the Examiner's rejection is clearly incorrect. As discussed above, the Applicant presumes that the rejection of claims 7, 16, 25 and 29 is based on a combination of Byram and Nelson and Darrow.

The undersigned called the Examiner on February 9, 2006 seeking clarification, but has not received any response clarifying this rejection. Therefore, the Applicant presumes that the rejection of claims 8, 9, 17, 18, 26, 27 is based on a combination of Byram and Nelson, and Darrow and Cruickshank, as that is the only rejection that would make sense.

Further, as discussed above, claim 30 depends from claim 28 and claim 29. As discussed above, the Applicant presumes that the rejection of claim 30 is properly based on a combination of Byram and Nelson and Darrow and Norfleet.

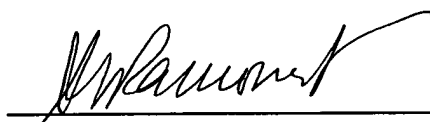
The undersigned called the Examiner on February 9, 2006 seeking clarification, but has not received any response clarifying this rejection. Therefore, the Applicant presumes that the rejection of claim 31 is based on a combination of Byram, and Nelson, and Darrow, and Norfleet and Cruickshank, as that is the only rejection that would make sense.

The Applicant submits that in view of the above arguments for claims 1-6, 10-15, 19-24 and 28, the rejection of claims 8, 9, 17, 18, 26, 27 and 31 is not relevant. Favorable consideration and withdrawal of the rejections to these claims under 35 U.S.C. 103 is respectfully requested.

Conclusions

In light of the arguments presented by Applicant herein, the Applicant submits that claims 1-31 are in a condition for allowance. Applicant respectfully requests that the Examiner withdraw all rejections with regard to the claims in reliance on one or more of the grounds submitted by the applicant.

Respectfully submitted,



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ATTACHMENTS:

1. Declaration of Dr. Lisa Semeniuk